EXHIBIT 1

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI

UNITED STATES OF AMERICA,

Plaintiff,

v.

CHRISTINA BECK, an individual

Defendant.

NO. 4:05CV02372CEJ

CONSENT DECREE OF PERMANENT INJUNCTION

The United States of America, Plaintiff, having filed a Complaint for Injunction against Defendant Christina Beck, an individual, and Defendant having waived service of process, appeared, and consented to the entry of this Decree in settlement of the injunctive action, without admitting the allegations in Plaintiff's complaint, and the United States of America having consented to this Decree in settlement of the injunctive action:

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that:

I. This Court has jurisdiction of this matter pursuant to 28 U.S.C. §§ 1331, 1337, and 1345 and 15 U.S.C § 1267(a) and has personal jurisdiction over Defendant. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

II. The Complaint for Injunction states a claim for relief against Defendant under the Federal Hazardous Substances Act ("FHSA"), 15 U.S.C. § 1261 *et seq.*, and the regulations issued thereunder.

III. For purposes of this Decree, the following definitions shall apply:

A. "Oxidizer" means potassium chlorate, sodium chlorate, potassium perchlorate, sodium perchlorate, potassium nitrate, sodium nitrate, or potassium permanganate.

B. "Fuel" means aluminum and aluminum alloys, magnesium, magnesium/aluminum alloy (magnalium), antimony sulfide, potassium benzoate, sodium benzoate, sodium salicylate, sulfur, titanium, zinc, or zirconium.

C. "Defendant" means Christina Beck, and each of her current and future owners, directors, officers, agents, employees, servants, attorneys, successor corporations, and those persons in active concert or participation with Defendant Beck.

D. "Banned hazardous substances" have the meaning set forth at 15 U.S.C. § 1261(q)(1), and include "[f]ireworks devices intended to produce audible effects (including but not limited to cherry bombs, M-80 salutes, silver salutes, and other large firecrackers, aerial bombs, and other fireworks designed to produce audible effects, and including kits and components intended to produce such fireworks) if the audible effect is produced by a charge of more than 2 grains of pyrotechnic composition. . . ." 16 C.F.R. § 1500.17(a)(3). They also include "[f]irecrackers designed to produce audible effects, if the audible effect is produced by a charge of more than 50 milligrams (.772 grains) of pyrotechnic composition . . . including kits and components intended to produce such fireworks . . . ." 16 C.F.R. § 1500.17(a)(8).

IV. Defendant is hereby permanently restrained and enjoined from participating in any transaction that involves receiving, selling, giving away, holding for sale, or otherwise distributing any oxidizer or fuel, as well as any fuse, tubes and end caps.

V. Defendant is hereby further permanently restrained and enjoined from violating 15 U.S.C. § 1263(a) by selling, giving away, or otherwise distributing any item where Defendant knows or has reason to believe that the recipient intends to use such item as a component of banned hazardous substances.

VI. If Defendant violates this Decree and is found in civil or criminal contempt thereof, Defendant shall, in addition to other remedies, reimburse plaintiff for its attorney fees (including overhead), investigational expenses, and court costs relating to any contempt proceedings.

VII. This Court retains jurisdiction of this action for the purposes of enforcing or modifying this Decree and for the purpose of granting such additional relief as hereafter may be necessary or appropriate.

December 22, 2005

UNITED STATES DISTRICT JUDGE

We hereby consent to entry of the foregoing Decree,

FOR THE PLAINTIFF:

PETER D. KEISLER
Assistant Attorney General

CATHERINE L. HANAWAY
United States Attorney

By: SUZETTE A. SMIKLE
Trial Attorney
Office of Consumer Litigation
P.O. Box 386
Washington, D.C. 20044
Phone: (202) 307-0052
Fax: (202) 514-8742

By: ALLISON H. BEHRENS
Assistant United States Attorney
111 South 10th Street, Room 20.333
St. Louis, Missouri 63102
(314) 539-2200

OF COUNSEL:

PAGE C. FAULK
General Counsel

HARRIET KERWIN
Attorney
U.S. Consumer Product Safety Commission
4330 East-West Highway
Bethesda, MD 20814-4408
(301) 504-7637

Dated: November 30, 2005

FOR THE DEFENDANT:

CHRISTINA BECK, individually

By: CLIFFORD SCHWARTZ, Esq.
Attorney at Law
7520 Forsyth Blvd.
Suite 200
St. Louis, MO 63105
Phone: (314) 863-6555
Fax: (314) 863-7773

Counsel for Defendant Christina Beck

EXHIBIT 2

TONY WEST
Assistant Attorney General

EUGENE M. THIROLF
Director, Office of Consumer Litigation

JOHN W. BURKE (VA. BAR NO. 72780)
Trial Attorney, Office of Consumer Litigation
Civil Division
United States Department of Justice
P.O. Box 386
Washington, D.C. 20044
Telephone: 202-353-2001
Facsimile: 202-514-8742
Email: josh.burke@usdoj.gov

Attorneys for Plaintiff United States of America

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, vs. DAISO HOLDING USA INC., A Washington corporation DAISO CALIFORNIA LLC, a California limited liability company, DAISO SEATTLE LLC, a Washington limited liability company, and YOSHIHIDE MURATA, as an officer of Daiso Holding USA Inc., Daiso California LLC, and Daiso Seattle LLC, Defendants.	Case No.: 4:10-cv-00795-PJH CONSENT DECREE FOR PERMANENT INJUNCTION AND PAYMENT OF CIVIL PENALTY

WHEREAS, Plaintiff, the United States of America, by its undersigned attorneys, has filed a Complaint against Daiso Holding USA Inc., Daiso California LLC, Daiso Seattle LLC, and Yoshihide Murata ("Defendants") to secure civil penalties and a permanent injunction for Defendants' alleged violations of statutes and regulations enforced by the Consumer Product

Safety Commission ("CPSC" or "Commission"), including Section 19 of the Consumer Product Safety Act ("CPSA"), 15 U.S.C. § 2068(a), and Section 4 of the Federal Hazardous Substances Act ("FHSA"), 15 U.S.C. § 1263;

WHEREAS, the parties having agreed to settlement of all allegations contained in the Complaint up to the date of the parties signing this Consent Decree for Permanent Injunction and Payment of Civil Penalty (the "Decree"), consent to entry of this Decree, and;

WHEREAS, Defendants have waived service of the Summons and Complaint; the parties are represented by the attorneys whose names appear hereafter; and the parties want to settle this action upon the following terms and conditions, before any testimony has been taken, without adjudication of any issue of fact or law, and;

WHEREAS, the Plaintiff believing settlement of this case on the terms described below is in the public interest given that this is the first and only action brought by the Plaintiff against the Defendants, and Defendants representing that they have not received any reports or consumer complaints regarding injuries or death resulting from the products at issue and expressly denying each and every of the Plaintiff's claims and allegations and believing settlement of this case is appropriate to avoid the time and expense of litigation so that Defendants may devote their resources to providing for the needs of their customers;

THEREFORE, on the agreement of the parties, it is hereby ORDERED, ADJUDGED AND DECREED as follows:

FINDINGS

1. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1345, and 1355(a).

2. This Court has jurisdiction, under 15 U.S.C. §§ 2071(a) and 1267(a), to restrain any violation of the CPSA and FHSA, and jurisdiction, under 15 U.S.C. §§ 2069 and 1264(c), to assess civil penalties for knowing violations of the CPSA and FHSA. All references to the CPSA and FHSA refer to those statutes as amended by the Consumer Product Safety Improvement Act of 2008, Public Law 110-314 ("CPSIA"), and all terms used herein shall have the same meaning as defined and used in the CPSA, CPSIA and FHSA.

3. Venue in the Northern District of California is proper under 28 U.S.C. §§ 1391(b), (c) and 1395(a).

4. At all times relevant hereto, Daiso Holding USA Inc., Daiso California LLC, and Daiso Seattle LLC were "manufacturers" and "retailers" of consumer products as defined in Section 3 of the CPSA, 15 U.S.C. § 2052(a).

5. At all times relevant hereto, Yoshihide Murata was Senior Vice-President for Daiso Holding USA Inc., Daiso California LLC, and Daiso Seattle LLC. At all times relevant, Murata knew of and had authority to control the acts and practices of Daiso Holding USA Inc., Daiso California LLC, and Daiso Seattle LLC regarding the importation and distribution of consumer products.

6. The Complaint states claims upon which relief may be granted against Defendants under Section 19 of the CPSA, 15 U.S.C. § 2068(a), and Section 4 of the FHSA, 15 U.S.C. § 1263.

7. The Complaint alleges that Defendants violate the CPSA, 15 U.S.C. § 2068(a)(1), by selling, offering for sale, manufacturing for sale, distributing in commerce, and importing into the United States consumer products, or other products or substances that are regulated under the CPSA or other Acts enforced by the Commission, that are not in conformity with an applicable consumer product safety rule under the CPSA, or any similar rule, regulation, standard or ban under any other Act enforced by the Commission. The Complaint alleges Defendants have violated the CPSA by distributing toys and other articles intended for use by children that bear lead-containing paint, prohibited under 16 C.F.R. § 1303.4(b); offering for sale and distributing in commerce children's toys or child care articles, as defined by 15 U.S.C. §§ 2057c(e)(1)(B) and (C), that contain phthalate concentrations exceeding the allowable amount; and by selling, offering for sale, and distributing in commerce products which are subject to consumer product safety rules and lack the conformity certificate required by 15 U.S.C. § 2063.

8. The Complaint alleges that Defendants violate the CPSA, 15 U.S.C. § 2068(a)(2)(D), and the FHSA, 15 U.S.C. §§ 1263(a) and (c), by introducing or causing the introduction and/or delivery for introduction into interstate commerce of banned hazardous substances, and/or the receipt in interstate commerce of banned hazardous substances and the delivery or proffered

delivery thereof for pay or otherwise, consisting of toys and other articles intended for use by children under 3 years of age which present a choking, aspiration, or ingestion hazard because of small parts, banned under 16 C.F.R. § 1500.18(a)(9); and children's products containing lead, banned under 15 U.S.C. § 1278a.

9. The Complaint alleges that Defendants violate the CPSA, 15 U.S.C. § 2068 (a)(4), by failing to furnish to the CPSC the information required by 15 U.S.C. § 2064(b).

10. The Complaint alleges that Defendants violate the FHSA, 15 U.S.C. §§ 1263(a) and (c), by introducing or causing the introduction and/or delivery for introduction into interstate commerce of misbranded hazardous substances, and/or the receipt in interstate commerce of misbranded hazardous substances and the delivery or proffered delivery thereof for pay or otherwise, consisting of toys or games intended for children at least three but not older than six years old that include a small part, which do not bear the cautionary statement specified under 15 U.S.C. § 1278(a)(2); latex balloons, or toys or games that contain a latex balloon, intended for children three years of age or older, which do not bear the cautionary statement specified under 15 U.S.C. § 1278(b)(2)(A); marbles, or toys or games that contain marbles, intended for children over three years of age or older, which do not bear the cautionary statements specified at 1278(b)(2)(C); and art materials or art material products which may have the potential to produce chronic adverse health effects, as defined under 16 C.F.R. § 1500.14(b)(8)(i)(B)(3), which do not meet the labeling requirements under 16 C.F.R. § 1500.14(b)(8)(i)(E).

11. Defendants deny the allegations of the Complaint and deny any other wrongdoing or violation of law, and have entered into this Decree freely and without coercion, in compromise of disputed claims, believing that settlement of this case is appropriate in order to avoid the time and expense of litigation.

12. Defendants hereby waive all rights to appeal or otherwise challenge or contest the validity of this Decree.

13. Entry of this Decree is in the public interest.

ORDER

IT IS THEREFORE ORDERED AS FOLLOWS:

1. IT IS THEREFORE ORDERED that Defendants, and each and all of their directors, officers, agents, brokers, employees, successors, assigns, and all persons or entities in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently enjoined from importing into the United States, directly or indirectly, introducing or causing the introduction into interstate commerce of any toy or other consumer product intended primarily for children 12 years of age or younger unless and until:

A. Defendants retain, at Defendants' expense, an independent person (the "Product Safety Coordinator" or "Coordinator"), who is without any personal or financial ties (other than the retention agreement) to Defendants and their families, and who, by reason of background, training, education, or experience, is qualified to help Defendants:

i. Create a comprehensive product safety program;

ii. Conduct a product audit to determine which of Defendants' merchandise requires testing and certification of compliance with the FHSA, the CPSA, and any other Act enforced by the CPSC;

iii. Establish and implement an effective and reasonable product safety testing program in compliance with the FHSA, the CPSA, and any other Act enforced by the CPSC;

iv. Retain, for art materials, a toxicologist listed on the CPSC website and/or an accredited testing laboratory provided on the CPSC website;

v. Retain for children's products a third party conformity assessment body or bodies listed on the CPSC's website to perform third party testing on children's products as required;

vi. Create guidance manuals for managers and employees on how to comply with product safety requirements;

vii. Advise Defendants on product labeling requirements;

viii. Establish procedures to conduct product recalls;

ix. Develop procedures for adhering to CPSC reporting requirements in 15 U.S.C. § 2064(b); and

x. Monitor Defendants' compliance with all applicable federal statutes, rules, and regulations enforced by the CPSC, during a monitoring period after Defendants resume importing and selling children's products.

B. Defendants submit the name and credentials of its Product Safety Coordinator to the CPSC's Office of Compliance and Field Operations ("Office of Compliance") via overnight delivery and facsimile, prior to using the Coordinator. If CPSC staff objects to the Coordinator selected by Defendants, the staff must so notify Defendants within thirty (30) calendar days of Defendants submitting the Coordinator's name and credentials, at which point Defendants shall select a replacement, the name and credentials of whom shall be submitted to the Office of Compliance. If CPSC staff does not respond to Defendants' submission of a Coordinator's credentials within 30 days, Defendants may use that Coordinator.

C. The Coordinator reviews Defendants' product inventory for safety violations and assesses Defendants' current regulatory compliance practices.

D. The Coordinator assists Defendants in establishing a comprehensive product safety program with written standard operating procedures ("SOPs") designed to ensure continuous compliance with applicable federal laws, standards, and regulations enforced by the CPSC. The product safety program shall:

i. Include the development of a reasonable testing program, pursuant to 15 U.S.C. § 2063 and applicable regulations, of all products that are subject to a children's product safety rule, or any other consumer product safety rule or similar ban, standard, or regulation under the CPSA, the FHSA, any other Act enforced by the CPSC, or any regulations passed thereunder;

ii. To the extent required by law, ensure that Defendants issue, after satisfactory testing, certificates of conformity for every consumer product that is subject to a consumer product safety rule, children's product safety rule, or similar ban,

standard, or regulation under the CPSA, the FHSA, any other Act enforced by the CPSC, or any regulations passed thereunder;

iii. Establish procedures to ensure Defendants apply all cautionary labeling required by the CPSA, the FHSA, any other Act enforced by the CPSA, and any applicable regulations;

iv. Establish systems to ensure that the product safety program's SOPs are consistently followed;

v. Include procedures to ensure that the Defendants adequately correct any product violation cited by a CPSC inspection and respond to CPSC letters of advice in the time specified in each letter of advice; and

vi. Establish systems to investigate all reports of consumer incidents, property damage, injuries, warranty claims, insurance claims and court complaints regarding products under the jurisdiction of the CPSC that Defendants imported into the United States.

E. The Defendants issue general conformity certificates for each consumer product that passes the applicable test, verifying that each of Defendants' consumer products complies with the applicable laws, standards and regulations to the extent required by 15 U.S.C. § 2063(a)(1), 16 C.F.R. Part 1110, and other applicable rules.

F. The Coordinator hires a qualified assessor to test children's products for compliance with children's product safety rules. A "qualified assessor" means any person or entity qualified to test the relevant product and for children's products it must be an accredited third party conformity assessment body that is listed on the CPSC's website for third party testing to the extent required by law. The Coordinator shall hire or supervise the hiring of a qualified assessor to test representative samples of each children's product subject to any children's product safety rule including, but not limited to, the following:

i. Small Parts: For each children's product that is intended for children under three years of age, as determined by age grading analysis that includes the

factors listed at 16 C.F.R. § 1501.2(b), and the CPSC's "Age Determination Guidelines: Relating Children's Ages to Toy Characteristics and Play Behavior," dated September 2002, and any updates, located on the CPSC's website, a qualified assessor shall review a model of each product to determine whether small parts exist and test each model of toy in accordance with the requirements of 16 C.F.R. §§ 1500.51, 1500.52 and 16 C.F.R. Part 1501. The children's product tested to the small parts requirement must meet the certification requirements at 73 FR § 67838-01;

ii. Lead Paint and Lead Content: To the extent required by law, a qualified assessor shall test each model of children's product that bears a surface coating for compliance with the lead paint requirements of 16 C.F.R. Part 1303, and test accessible substrates, when applicable, for lead content requirements of 15 U.S.C. § 1278a(b)(2). In addition, each model of toy designed or intended primarily for children 12 years of age or younger shall be tested in accordance with the applicable requirements of the effective version of American Society for Testing and Materials standard F963-08. The qualified assessor must be accredited to certify to the requirements for lead paint testing, 16 C.F.R. Part 1303, which appear at 73 FR § 54564-6 or such later-adopted requirements as are then applicable, and the certification requirement for testing children's products for lead content, 15 U.S.C. § 1278a, which appear at 73 FR § 78331-06 or such later-adopted requirements as are then applicable; and

iii. Phthalates: A qualified assessor shall test each model of children's toy or child care article for compliance with the phthalate content requirements of 15 U.S.C. § 2057c. The qualified assessor shall test the toys/articles in accordance with the "Standard Operating Procedure for Determination of Phthalates" dated March 3, 2009, CPSC-CH-C1001-09.1, located on the CPSC website, or in accordance with one of the alternative methods described therein or such later-adopted requirements as are then applicable.

G. The Defendants issue certificates of compliance for each children's product that is subject to any children's product safety rule, verifying that each of the Defendants' children's products complies with such children's product safety rule, to the extent required by 15 U.S.C. § 2063(a)(2), 16 C.F.R. Part 1110, and other applicable rules or stays of enforcement, based on testing by a third party accredited laboratory.

H. The Coordinator inspects a random selection of a representative sample of all consumer products in Defendants' inventory for compliance with all labeling requirements imposed by the CPSA, the FHSA, any other Act enforced by the CPSC, and all applicable regulations, including but not limited to the following:

i. Small Parts: For each children's toy that is intended for children over three years of age and under six years of age, Defendants shall apply cautionary labeling to each such item consistent with the requirements of 15 U.S.C. §§ 1278(a) and (b); and

ii. Art Materials: In determining whether an art material or art material product has the potential for producing chronic adverse health effects, Defendants shall have a qualified assessor analyze the formulation of the art materials, taking into account opinions of the relevant regulatory agencies and scientific institutions, as required under 15 U.S.C. § 1277(b)(8), and also the factors listed in 16 C.F.R. § 1500.14(b)(8)(i)(D)(2). The qualified assessor for this subsection shall be a toxicologist listed on the CPSC website. For each art material or art material product Defendants shall apply labeling to each such item consistent with the requirements in 16 C.F.R. § 1500.14(b)(8)(i)(C).

I. Defendants recall, at least to the retail level, all defective and non-complying products they have distributed or received in commerce on or after January 1, 2010, under the direction and supervision of the Office of Compliance. For consumer level recalls Defendants shall at least: post recall notices when warranted; send signs to all retailers and instruct them to post them in a prominent place for 120 days; if known directly contact the consumers who purchased the recalled products; and destroy the

recalled items in accordance with local and/or state environmental regulations under the supervision of the Office of Compliance.

J. The Coordinator certifies in writing, to the Office of Compliance, that:

i. Defendants have established a comprehensive product safety program, including a reasonable testing program, and internal policies for implementing that program;

ii. Defendants have corrected the safety violations brought to Defendants' attention by the CPSC, the Coordinator, and any other source;

iii. Defendants have recalled all defective, potentially hazardous and non-complying consumer products as instructed by the Office of Compliance;

iv. The Coordinator has identified each product in Defendants' product inventory that is subject to a consumer product safety rule or similar rule, ban, standard, or regulation under the CPSA, the FHSA, or any other Act enforced by the CPSC;

v. All identified products have been tested for compliance with all applicable rules, bans, standards, or regulations as required by 15 U.S.C. § 2063(a)(1) and (a)(2);

vi. All art material formulations shall be submitted to a toxicologist listed on the CPSC website for review and the toxicologist's criteria sent to the Office of Compliance staff, as required by 16 C.F.R. §1500.14(b)(8)(i)(C);

vii. To the extent required by law, and subject to any applicable stay of enforcement now existing or adopted in the future, for each such product that passes the required testing, Defendants have issued a certificate that certifies that such consumer product complies with all rules, bans, standards, or regulations applicable to the product under the CPSA, the FHSA, and any other Act enforced by the Commission;

viii. The Coordinator has identified and provided a list of each product in Defendants' inventory or that Defendants intend to import for consumption,

warehousing, or distribution in the United States that is a children's product subject to a children's product safety rule;

ix. Defendants have submitted samples of each such children's product to a qualified assessor for compliance testing;

x. For each such product that meets the requirements of applicable standards, regulations, or bans through the third party testing, Defendants have issued a certificate for each applicable children's product safety rule, certifying that such children's product complies with each children's product safety rule based on testing by a third party conformity assessment body accredited to conduct such testing;

xi. Defendants have reconditioned or destroyed with CPSC staff guidance and supervision all consumer products, including children's products, in its inventory, that failed to meet any applicable consumer product safety rule, ban, standard, or regulation; and

xii. Defendants have applied cautionary labeling to all products for which such labeling is required under the CPSA, the FHSA, any other Act enforced by the CPSC, and all applicable regulations.

K. CPSC representatives inspect Defendants' facilities to determine whether the requirements of this Decree have been met. This inspection shall occur as soon as practicable after the CPSC's receipt of the Coordinator's report under subparagraph (J).

L. The CPSC notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in subparagraphs (A) – (J) of this Decree. CPSC's silence shall not be construed as a substitute for written notification unless the CPSC fails to respond to a written request from Defendants for a notice under this paragraph within thirty (30) days of the request.

2. For a period of at least one year from the date the CPSC notifies Defendants in writing pursuant to subparagraph (1)(L) (the "monitoring period"), Defendants shall retain the Product

Safety Coordinator to monitor Defendants' implementation of the comprehensive product safety program and compliance with the requirements of this Decree and all relevant statutes and regulations. At the end of the first year of the monitoring period and at the end of any 180-day extension of the monitoring period under this paragraph, the Coordinator shall provide a written report to the Office of Compliance. If the Coordinator certifies Defendants are in compliance as described in this paragraph, the monitoring period will end. If the Coordinator cannot certify that Defendants meet each of the compliance requirements listed below, the monitoring period shall continue for an additional 180 days, at the end of which the Coordinator shall provide an updated written report to the Office of Compliance. To meet the requirements of this paragraph and terminate the monitoring period, the Coordinator must certify, in writing, to the Office of Compliance, the following:

A. Defendants are in compliance with the comprehensive product safety program established under paragraph (1)(A), including the reasonable testing program required by 15 U.S.C. § 2063.

B. Subsequent to the Coordinator's most recent written report under this paragraph or paragraph (1)(J), Defendants have:

i. Issued conformity certificates, after appropriate testing, for each consumer product or model that is subject to a consumer product safety rule and is imported for consumption, warehousing or distribution in commerce, to the extent required by then-applicable law;

ii. Before importing for consumption, warehousing or distributing in commerce, any children's product or model of any children's product that is subject to any children's product safety rule, submitted samples of that product to a qualified assessor to be tested for compliance with any applicable children's product safety rule; and

iii. Based on such third party testing, issued conformity certificates for each such children's product to the extent required by then-applicable law.

C. Defendants have complied with all labeling requirements imposed by the CPSA, the FHSA, any other Act enforced by the CPSC, and all regulations imposed thereunder.

D. Defendants have complied with all reporting requirements imposed by the CPSA, the FHSA, any other Act enforced by the CPSC, and all regulations imposed thereunder.

E. Defendants have not violated any provision of this Decree, the CPSA, the FHSA, any other Act enforced by the CPSC, and all regulations imposed thereunder.

3. To facilitate the monitoring required by paragraph 2:

A. Defendants shall provide to the Coordinator, copies of the following items, within fourteen (14) days of Defendants obtaining or issuing any of the following:

i. Results of any test conducted as part of the Defendants' reasonable testing program to determine compliance with any consumer product safety rule, regulation, ban, or standard under any Act enforced by the CPSC;

ii. Results of any third party testing conducted before importation, of any children's product that is subject to a children's product safety rule; and

iii. Any certificates of conformity issued by Defendants for any consumer product or children's product.

B. Defendants shall report to the Coordinator:

i. A list of all children's products, including descriptions, model numbers, and UPC codes, which Defendants import into the United States, within five (5) days of such importation; and

ii. Any report of an incident that involved injury or the potential for injury caused by any product imported or sold by Defendants, within five (5) days of Defendants' receipt of such report. This requirement shall be separate from, and in addition to, any reporting requirement imposed on Defendants by the CPSA, the FHSA, any other Act enforced by the CPSC, and all regulations imposed thereunder.

4. Defendants, and each and all of their directors, officers, agents, brokers, employees, successors, assigns, and all persons or entities in active concert or participation with any of them

who receive actual notice of this Decree by personal service or otherwise, are hereby permanently restrained and enjoined from directly or indirectly doing or causing to be done any of the following acts:

Violating the CPSA

A. Violating Section 19(a) of the CPSA, 15 U.S.C. § 2068(a), by selling, offering for sale, manufacturing for sale, distributing in commerce, or importing into the United States any consumer product, or other product or substance that is regulated under the CPSA or any other Act enforced by the Commission, that is not in conformity with an applicable consumer product safety rule under the CPSA, or any similar rule, regulation, standard, or ban under any Act enforced by the Commission, including but not limited to:

   i. Any children's toys or child care articles that contain excessive concentrations of phthalates in violation of 15 U.S.C. § 2057c;

   ii. Any product which is subject to any consumer product safety rule or any children's product safety rule and lacks a conformity certificate to the extent required under 15 U.S.C. § 2063 and applicable rules, regulations and enforcement policies of the CPSC; and

   iii. Children's products which have not been tested by a third party conformity assessment body to the extent required under 15 U.S.C. § 2063(a)(2) and applicable rules, regulations and enforcement policies of the CPSC;

B. Violating Section 19(a)(2)(D) of the CPSA, 15 U.S.C. § 2068(a)(2)(D) by selling, offering for sale, manufacturing for sale, distributing in commerce, or importing into the United States any consumer product, or other product or substance that is a banned hazardous substance within the meaning of section 2(q)(1) of the Federal Hazardous Substances Act (15 U.S.C. 1261(q)(1)), including, but not limited to the violations discussed in subparagraphs (E) – (F) below.

C. Violating Section 19(a)(4) of the CPSA, 15 U.S.C. § 2068(a)(4), by failing to furnish to the CPSC information required by Section 15(b) of the CPSA, 15 U.S.C. § 2064(b).

D. Engaging in any other act or practice that would violate the CPSA, 15 U.S.C. § 2051 et seq., as limited by any applicable rules, regulations and enforcement policies of the CPSC.

Violating the FHSA

E. Introducing, or causing the introduction and/or delivery for introduction into interstate commerce, any banned hazardous substance and/or receiving in interstate commerce any banned hazardous substances or delivering or proffering to deliver thereof for pay or otherwise, in violation of Section 4 of the FHSA, 15 U.S.C. §§ 1263(a) and (c), including, but not limited to:

i. Any children's product containing lead exceeding the limits established in 15 U.S.C. § 1278a;

ii. Any toy or other article intended for use by children that bears lead-containing paint, as defined by 16 C.F.R. § 1303.2(b); and

iii. Any toy or other article, intended for use by children under 3 years of age that presents a choking, aspiration, or ingestion hazard because of small parts as defined by 16 C.F.R. Part 1501.

F. Introducing, or causing the introduction and/or delivery for introduction into interstate commerce of any misbranded hazardous substance and/or receiving in interstate commerce any misbranded hazardous substance or delivering or proffering to deliver thereof for pay or otherwise, in violation of Section 4 of the FHSA, 15 U.S.C. § 1263(a) and (c), including, but not limited to:

i. Any toy or game intended for children at least three but not older than six years old that includes a small part, as defined under 16 C.F.R. Part 1501, which does not bear the cautionary statement required under 15 U.S.C. § 1278(a)(2);

ii. Any latex balloon, small ball, or marble, or any toy or game containing a latex balloon, small ball, or marble, intended for children three years of age or older, which does not bear the appropriate cautionary statement, as required under 15 U.S.C. § 1278(b); and

iii. Any art material or art material product which does not meet the requirements defined under 16 C.F.R. § 1500.14(b)(8)(i)(C), which does not bear at the least the statement required by 16 C.F.R. § 1500.14(b)(8)(i)(C)(7).

G. Engaging in any other act or practice that would violate the FHSA, 15 U.S.C. § 1261 et seq.

5. Defendants shall file entry summary documentation with estimated duties attached on all of its entries before Defendants can obtain release of its merchandise from U.S. Customs and Border Protection custody.

6. Defendants shall maintain, in their United States offices, records of all analyses, testing, and certificates of conformance for any consumer product required by this Decree and all applicable laws. Such records shall include, but not be limited to, the date of the analysis and testing, the procedures used, and the results of the analysis and testing. Defendants shall also maintain, in their United States offices, records of all consumer incidents, property damage, injuries, warranty claims, insurance claims or court complaints regarding consumer products Defendants imported into the United States, regardless of where the incident occurred, to the extent reasonably available and permitted by law

7. Representatives of the CPSC shall be permitted, without prior notice and as and when the CPSC deems necessary, to make inspections of Defendants' place(s) of business, and take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, CPSC representatives shall be permitted immediate access to Defendants' place(s) of business, including, but not limited to, all buildings, equipment, computer or electronic files, containers, labeling, and other promotional material therein; to take photographs and make video recordings; to take samples of Defendants' products, containers, labeling, and other promotional material; and to examine and copy all records, including

electronic records, relating to the packing, labeling, holding, and distribution of any and all toys and other articles intended for use by children in order to ensure continuing compliance with the terms of this Decree. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the CPSA, 15 U.S.C. § 2065(a), FHSA, 15 U.S.C. § 1270, and any other Act administered by the CPSC. In addition, in order to ensure Defendants' compliance with this Decree, Plaintiff and the CPSC are authorized to monitor Defendants' compliance with this Decree by all lawful means, including but not limited to, using representatives posing as consumers to contact Defendants' websites, employees, and representatives, and/or any other person or entity managed or controlled in whole or in part by Defendants, without the necessity of identification or prior notice.

8. Defendants shall reimburse the CPSC for the costs of the inspection required under subparagraph (1)(K), at the standard rates charged by the Food and Drug Administration ("FDA") at the time the activities are accomplished. As of the date of entry of this Decree, these rates are: $85.49 per hour or fraction thereof per representative for inspection and investigative work; $102.49 per hour or fraction thereof per representative for laboratory and analytical work; $0.55 per mile for travel expenses by automobile, government rate or the equivalent for travel by air; and the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court. Nothing in this Decree shall limit the ability of Plaintiff or the CPSC to obtain costs from Defendants for additional supervision as provided by law. In addition, should Plaintiff bring, and prevail in, a contempt action against any Defendant(s) to enforce the terms of this Decree, such Defendant(s) shall pay all attorneys' fees and costs, travel expenses incurred by attorneys and witnesses, expert witness fees, investigational and analytical expenses, and court costs incurred by Plaintiff in bringing such an action.

9. Within ten (10) calendar days of the entry of this Decree, Defendants shall post a copy of this Decree on a bulletin board in a common area at its Hayward, CA corporate and warehouse

facilities, at its retail locations, and at any other location at which Defendants conduct business within the CPSC's jurisdiction, and shall ensure that the Decree remains posted at each location for as long as the Decree remains in effect.

10. Within ten (10) calendar days of the date of entry of this Decree, Defendants shall provide a copy of the Decree, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of their directors, officers, and the general managers of each retail location in the United States (collectively referred to as "Associated Persons"). Within thirty (30) calendar days of the date of entry of this Decree, Defendants shall provide to the CPSC Office of the General Counsel an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all persons who received a copy of this Decree pursuant to this paragraph.

11. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Decree, such Defendant(s) immediately shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Within ten (10) calendar days of each time any of the Defendants becomes associated with any such additional Associated Person, such Defendant(s) shall provide, to the CPSC Office of the General Counsel, an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of any Associated Person(s) who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts.

12. Within ten (10) calendar days of receiving a request from the CPSC for any information or documentation that the CPSC deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to the CPSC.

13. Defendants shall notify the CPSC Office of the General Counsel in writing at least ten (10) calendar days prior to any reorganization, dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of any subsidiaries, or any other changes in its corporate structure, including the addition of importer of record numbers, that may affect compliance obligations arising out of this Decree.

14. All notifications, correspondence, and communications to the CPSC required by the terms of this Decree shall be addressed to the CPSC, Director, Division of Regulatory Enforcement, Office of Compliance and Field Operations, 4330 East West Highway, Bethesda, MD 20814 or the CPSC, Office of the General Counsel, 4330 East West Highway, Bethesda, MD 20814, as directed.

15. Defendants Daiso Holding USA Inc., Daiso California LLC, and Daiso Seattle LLC shall pay two million, fifty thousand dollars ($2,050,000) to the United States as a civil penalty, pursuant to 15 U.S.C. §§ 1264(c) and 2069. The civil penalty shall be paid within ten (10) business days after the Court's entry of this Decree. Payment shall be made by wire transfer or certified or cashier's check made payable to the Treasurer of the United States. The check or written confirmation of the wire transfer shall be delivered to: Director, Office of Consumer Litigation, U.S. Department of Justice Civil Division, P.O. Box 386, Washington, D.C. 20044. The cover letter accompanying the wire transfer or check shall include the title of this litigation and a reference to DJ # 104-11-50.

16. In the event of any default on the payment required in Paragraph 15, which default continues for ten (10) calendar days beyond the due date of the payment, Defendants shall pay Plaintiff interest on the amount owing at a rate compounded pursuant to 28 U.S.C. § 1961(a), except that Defendants shall not be required to pay interest on any interest due.

17. Provided that Defendants make the payment due under paragraph 15 hereof, and are not in default of any other obligation under this Consent Decree, the Justice Department's Office of Consumer Litigation and the CPSC agree not to file further actions of any kind or nature, or initiate any administrative proceedings, under the CPSA, FHSA, or other statutes administered by the CPSC, against any Defendant or any individual, employee, representative or agent of any Defendant or any affiliated entity for conduct relating to selling, offering for sale, manufacturing for sale, distributing in commerce, or importing into the United States consumer products that are not in conformity with an applicable consumer product safety rule or similar rule, regulation, standard or ban under a statute enforced by the Commission, or any banned, misbranded or mislabeled hazardous substance during the period from January 1, 2005, to the date that the

parties sign this Decree, or for any other alleged violation by Defendants of the CPSA, the FHSA or other statutes administered by the CPSC based upon information known to the CPSC during the period January 1, 2005, to the date that the parties sign this Decree. Nothing in this paragraph shall effect, revive, or extend any applicable statute of limitations with respect to any actual or alleged violations by Defendants of the CPSA, the FHSA, or other statutes administered by the CPSC.

18. If any Defendant fails to comply with the material provisions of this Decree, that Defendant shall pay to the United States of America liquidated damages in the sum of one thousand dollars ($1,000.00) for each day that the Defendant fails to comply with this Decree. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and that they do not in any way limit the ability of the United States of America to seek, and the Court to impose, additional criminal or civil contempt penalties based on conduct that may also be the basis for the payment of liquidated damages.

19. This Consent Decree, and any act, statement or document executed pursuant to or in furtherance of it, shall not be deemed or used in any way: (i) as an admission of, or evidence of, the validity of any claim asserted in the Complaint, or of any wrongdoing or liability of any Defendant, or of any unlawful, unfair or fraudulent business practices of any Defendant, all of which are denied; (ii) as an admission of, or evidence of, any fault of omission of any Defendant in any civil, criminal or administrative proceeding of any kind in any court, administrative agency or other tribunal; or (iii) as an admission of, waiver of, or evidence relating to, any claim or defense asserted by any party.

20. Each party shall bear its own costs and attorney's fees.

21. The provisions of this Decree are separate and severable from one another. If any provision is stayed or determined to be invalid, the remaining provisions shall remain in full force and effect.

22. Defendants may petition this Court to rescind the provisions of this Decree, except the permanent injunction in paragraph 4, after a period of ten (10) years from the entry of this Decree. If, in the Commission staff's judgment, Defendants and their successors have

maintained a state of continuous compliance with this Decree, Plaintiff will not oppose such petition.

23. The terms used herein shall be interpreted as they are used in the CPSA, CPSIA, FHSA and other acts enforced by the Commission as may be applicable, and in any official rules, regulations and interpretations thereof.

24. The parties note that the CPSA, CPSIA, FHSA and other laws, standards and regulations enforced by the Commission that govern this Decree, are subject to amendment or repeal by act of Congress or by other means, as well as stays of enforcement, exemptions, determinations, Commission rulings and other acts or events that may materially modify the rights and obligations of the parties. The parties and the Court intend that this Decree shall not require any of the Defendants to obey or comply with any legal requirement stated or relied upon herein to the extent its enforcement is stayed or limited or to the extent it is amended, repealed or otherwise materially modified or rendered not enforceable as to parties in Defendants' circumstances.

25. This Court shall retain jurisdiction of this matter for purposes of construction, modification, and enforcement of this Decree.

26. The parties, by their respective counsel, hereby consent to entry of the foregoing Decree, which shall constitute a final judgment and order in this matter. The parties further stipulate and agree that the entry of the foregoing Decree shall constitute full, complete, and final settlement of this action.

SO ORDERED this 4th day of March, 2010.

United States District Judge

UNITED STATES DISTRICT COURT
IT IS SO ORDERED
Judge Phyllis J. Hamilton
NORTHERN DISTRICT OF CALIFORNIA

FOR PLAINTIFF
UNITED STATES OF AMERICA:

TONY WEST
Assistant Attorney General
Civil Division
U.S. Department of Justice

EUGENE M. THIROLF
Director, Office of Consumer Litigation

/s/ _____
JOHN W. BURKE (VA. BAR NO. 72780)
Trial Attorney
Office of Consumer Litigation
Civil Division
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
Telephone: 202-353-2001
Facsimile: 202-514-8742
Email: josh.burke@usdoj.gov

OF COUNSEL:

CHERYL A. FALVEY
General Counsel
U.S. Consumer Product Safety Commission

HARRIET KERWIN
Attorney
Office of the General Counsel
U.S. Consumer Product Safety Commission
Bethesda, MD 20814

FOR THE DEFENDANTS:

/s/ _____

PAUL S. ROSENLUND
DUANE MORRIS LLP
One Market, Spear Tower, Suite 2200
San Francisco, CA 94105-1127
Telephone: 415-957-3178
Facsimile: 415-520-5479
Email: psrosenlund@duanemorris.com
Counsel for Defendants DAISO HOLDING USA INC., DAISO CALIFORNIA LLC, and DAISO SEATTLE LLC

BY: /s/ _____
DAISO HOLDING USA INC.
DAISO CALIFORNIA LLC
DAISO SEATTLE LLC
26523 Danti Court
Hayward, CA 94545

/s/ _____
YOSHIHIDE MURATA,
Vice President of Daiso Holding USA Inc., Daiso California LLC, and Daiso Seattle LLC

ATTESTATION OF CONCURRENCE IN FILING

United States v. Daiso Holding USA, Inc., et al., No. 4:10-cv-00795-PJH (N.D. Cal.)

In accord with the Northern District of California's General Order No. 45, Section X.(B), I attest that concurrence in the filing of this document has been obtained from each of the other signatories who are listed on the signature pages.

Dated: March 2, 2010

/S/ John W. Burke
JOHN W. BURKE (VA Bar No. 72780)
Trial Attorney
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044
(202) 353-2001
josh.burke@usdoj.gov

EXHIBIT 3

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. FREDERICK A. ELLIS, aka RICK ELLIS, an individual; and PYROWORKS, LLC, a Missouri corporation, Defendants.	)	Case. No. 4:06-cv-127 (CEJ)

CONSENT DECREE OF PERMANENT INJUNCTION

The United States of America, Plaintiff, having filed a Complaint for Injunction against Defendants Frederick A. Ellis, an individual, and PyroWorks, LLC, a Missouri corporation, and Defendants having appeared, and consented to the entry of this Decree in settlement of the injunctive action, without admitting the allegations in Plaintiff's complaint, and the United States of America having consented to this Decree in settlement of the injunctive action:

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that:

I. This Court has jurisdiction of this matter pursuant to 28 U.S.C. §§ 1331, 1337, and 1345 and 15 U.S.C § 1267(a) and has personal jurisdiction over Defendants. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

II. The Complaint for Injunction states a claim for relief against Defendants under the Federal Hazardous Substances Act ("FHSA"), 15 U.S.C. § 1261 *et seq.*, and the regulations issued thereunder.

III. For purposes of this Decree, the following definitions shall apply:

A. "Oxidizer" means potassium chlorate, sodium chlorate, potassium perchlorate, sodium perchlorate, potassium nitrate, sodium nitrate, or potassium permanganate.

B. "Fuel" means aluminum and aluminum alloys, magnesium, magnesium/aluminum alloy (magnalium), antimony sulfide, potassium benzoate, sodium benzoate, sodium salicylate, sulfur, titanium, zinc, or zirconium.

C. "Defendants" mean Frederick A. Ellis and PyroWorks, LLC, and each of their current and future owners, directors, officers, agents, employees, servants, attorneys, successor corporations, and those persons in active concert or participation with any of them.

D. "Banned hazardous substances" have the meaning set forth at 15 U.S.C. § 1261(q)(1), and include "[f]ireworks devices intended to produce audible effects (including but not limited to cherry bombs, M-80 salutes, silver salutes, and other large firecrackers, aerial bombs, and other fireworks designed to produce audible effects, and including kits and components intended to produce such fireworks) if the audible effect is produced by a charge of more than 2 grains of pyrotechnic composition. . . ." 16 C.F.R. § 1500.17(a)(3). They also include "[f]irecrackers designed to produce audible effects, if the audible effect is produced by a charge of more than 50 milligrams (.772 grains) of pyrotechnic composition . . . including kits and components intended to produce such fireworks . . . ." 16 C.F.R. § 1500.17(a)(8).

IV. Upon complying with paragraph VI of this Decree, Defendants are hereby permanently restrained and enjoined from participating in any transaction that involves

receiving, selling, giving away, holding for sale, or otherwise distributing any oxidizer or fuel, as well as any tubes, fuse and end caps.

V. Defendants are hereby further permanently restrained and enjoined from violating 15 U.S.C. § 1263(a) by selling, giving away, or otherwise distributing any item where Defendants know or have reason to believe that the recipient intends to use such item as a component of banned hazardous substances.

VI. Within sixty (60) calendar days of the entry of this Decree, Defendants shall destroy, at their own cost, the inventory of fireworks components currently in their control and possession. Within twenty (20) calendar days of destroying their fireworks components, Defendants shall submit to the Director of OCL a declaration of compliance that is consistent with 28 U.S.C. § 1746 and signed under penalty of perjury by Defendant Frederick Ellis, and that sets forth precisely what fireworks components were destroyed.

VII. To ensure continuing compliance with the terms of this Decree, investigators with the United States Consumer Product Safety Commission ("CPSC") shall be authorized to make inspections, at their discretion and without prior notice, of Defendants' facilities and records therein, and to take samples, copies of documents, and photographs. Such inspection authority granted by this Decree is apart from and in addition to the authority to make inspections under 15 U.S.C. §§ 1270 and 1271. Such inspections shall be authorized upon presentation of a copy of this Decree and government credentials. During any such inspections, Defendants shall cooperate fully with the CPSC investigators by, among other things, promptly providing any investigator with all requested documents and immediate access to any of Defendants' facilities.

VIII. Defendants shall serve a copy of this Decree, by personal service or registered mail, within ten (10) calendar days of its entry, upon all current owners, officers, directors,

agents, servants, employees, and consignees of PyroWorks, LLC, and shall provide CPSC with an affidavit of compliance with this paragraph, signed under penalty of perjury by Defendant Frederick Ellis, within thirty (30) calendar days of such entry, stating the fact and manner of compliance and identifying the names and positions of all persons so notified. Defendants shall likewise serve a copy of this Decree, by personal service or registered mail, upon any new officer, director, agent, servant, employee, or consignee of PyroWorks LLC within thirty (30) calendar days of the date on which that individual enters into a business relationship with Defendants, and shall provide CPSC with an affidavit of compliance with this paragraph, signed under penalty of perjury by Defendant Frederick Ellis within thirty (30) calendar days of such service, stating the fact and manner of compliance and identifying the names and positions of all persons so notified.

IX. Defendants shall notify CPSC at least ten (10) calendar days before any reorganization, relocation, or dissolution of the corporate Defendant; any sale, lease, or transfer of assets resulting in the emergence of a successor business; the creation or dissolution of subsidiaries or affiliates; or any change in the corporate Defendant's manner of operation or in the employment of the individual Defendant that could affect compliance obligations arising out of this Decree.

X. If any Defendant violates this Decree and is found in civil or criminal contempt thereof, such Defendant shall, in addition to other remedies, reimburse plaintiff for its attorney fees (including overhead), investigational expenses, and court costs relating to any contempt proceedings.

XI. All notifications, correspondence, and communications to the CPSC required by this Decree shall be addressed to: (a) the Director of Compliance, United States Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, Maryland 20814 (Facsimile

Number 301-504-0359), or (b) to such other addresses or facsimile numbers as CPSC may later provide in writing to Defendants.

XII. This Court retains jurisdiction of this action for the purposes of enforcing or modifying this Decree and for the purpose of granting such additional relief as hereafter may be necessary or appropriate.

Dated this 1st day of June, 2006.

Carol E. Jackson

THE HONORABLE CAROL E. JACKSON
UNITED STATES DISTRICT JUDGE

We hereby consent to entry of the foregoing Decree,

FOR THE PLAINTIFF:

PETER D. KEISLER
Assistant Attorney General

CATHERINE L. HANAWAY
United States Attorney

By: SUZETTE A. SMIKLE
Trial Attorney
Office of Consumer Litigation
P.O. Box 386
Washington, D.C. 20044
Phone: (202) 307-0052
Fax: (202) 514-8742

Dated: 5/23/06

ALLISON H. BEHRENS
Assistant United States Attorney
111 South 10th Street, Room 20.333
St. Louis, Missouri 63102
(314) 539-2200

Attorneys for Plaintiff United States of America

OF COUNSEL:

PAGE C. FAULK
General Counsel

HARRIET KERWIN
Attorney
U.S. Consumer Product Safety Commission
4330 East-West Highway
Bethesda, MD 20814-4408
(301) 504-7637

FOR THE DEFENDANTS:

FREDERICK A. ELLIS, individually, and as President and Owner of PYROWORKS, LLC.

Dated: 5-18-06

JOHN H. BROOKE
DOUGLAS MAWHORR
Brooke, Mawhorr, P.C.
112 East Gilbert Street
P.O. Box 1071
Muncie, Indiana 47308
Phone: (765) 741-1375

Dated: 5/22/06

BURTON H. SHOSTAK
Moline, Shostak & Mehan, LLC
8015 Forsyth Blvd.
St. Louis, MO 63105
Phone: (314) 725-3275

Attorneys for Defendants Frederick A. Ellis and PyroWorks, LLC.

EXHIBIT 4

Slip Copy, 2009 WL 3111815 (M.D.Fla.)
(Cite as: 2009 WL 3111815 (M.D.Fla.))

H

Only the Westlaw citation is currently available.

United States District Court, M.D. Florida, Orlando Division.
UNITED STATES of America, Plaintiff,
v.
ENDOTEC, INC., Michael J. Pappas, Frederick F. Buechel, Jared Pappas, Defendants.
No. 6:06-cv-1281-Orl-18KRS.

Sept. 28, 2009.

West KeySummary
Health 198H ⇐318

198H Health
198HI Regulation in General
198HI(E) Drugs; Medical Devices and Instruments
198Hk315 Applications and Approvals
198Hk318 k. Exemptions. Most Cited Cases
A doctor violated the Food, Drug and Cosmetic Act (FDCA) by exceeding the scope of an approved clinical study of an ankle device. The FDA approved a limited clinical study of an ankle device designed by the doctor. However, the doctor admitted that he was not a clinical investigator and could not implant the device pursuant to approved clinical study. Despite this, the doctor admitted that he implanted the ankle device on an unknown number of patients prior to receiving a warning letter from the Food and Drug Administration. The doctor occasionally continued to implant the device even after receiving the letter. Federal Food, Drug, and Cosmetic Act, §§ 301(q)(l), 501(i), 21 U.S.C.A. §§ 331(q)(l), 351(i).

Gerald C. Kell, Office of Consumer Litigation, Washington, DC, Javier M. Guzman, U.S. Attorney's Office, Tampa, FL, for Plaintiff.

Vello Veski, Law Office of Vello Veski, Palm City, FL, for Defendants.

ORDER

G. KENDALL SHARP, Senior District Judge.

*1 THIS CAUSE comes before the Court upon remand from the United States Court of Appeals for the Eleventh Circuit. *United States v. Endotec, Inc.*, 563 F.3d 1187 (11th Cir.2009).

I. BACKGROUND

A full recitation of the underlying facts can be found in this Court's prior Order of April 30.2008. (Doc. 100. filed Apr. 30, 2008.) Briefly, the United States of America ("the Government") brought this civil action seeking a permanent injunction against Endotec. Inc. as well as Michael Pappas and Frederick F. Buechel, its two owners (collectively "Defendants"). The Government alleges that Defendants violated the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* by (1) manufacturing and distributing adulterated ankle, knee, and jaw devices, and (2) exceeding the scope of an approved clinical study of an ankle device. After a bench trial, this Court enjoined Defendants from manufacturing and distributing the knee devices but refused to do so for the ankle and jaw devices. This Court further found that Defendants had not violated the clinical study of the ankle device. *United States v. Endotec, Inc.*, No. 6:06-1281, 2008 U.S. Dist. LEXIS 35427, 2008 WL 1909164 (M.D.Fla. Apr. 30, 2008). The ankle device at issue is the Buechel-Pappas Total Ankle Replacement System ("B-P Ankle") and includes: (1) all ankle devices distributed by Defendants for use in patients beyond the scope of the clinical study for the B-P Ankle, and (2) all ankle devices distributed as "custom" or "surgeon specials."

On appeal, the Eleventh Circuit affirmed this Court's decision regarding the knee and jaw devices. As to the ankle device, however, the court of appeals reversed this Court's decision and remanded the matter in two respects. First, the Elev-

enth Circuit found that this court abused its discretion in denying the Government's request for a permanent injunction. *Endotec,* 563 F.3d at 1197-1200. Second, the Eleventh Circuit determined that this Court employed faulty reasoning in finding that Defendants had not violated the scope of the clinical study. *Id.* at 1200-03. On April 21, 2009, this Court entered a permanent injunction prohibiting Defendants from manufacturing, packing, labeling and distributing the B-P Ankle. This Court also requested that the parties provide supplemental briefing addressing: (1) whether Defendants violated sections 21 U.S.C. §§ 351(i), 331(q) through the manufacture and distribution of the B-P Ankle outside the IDE clinical study based on the record evidence; (2) whether this issue as to the IDE study is now moot in light of the fact that the Food and Drug Administration ("FDA") has lifted the Application Integrity Policy ("AIP"): and (3) any other issues related to the IDE clinical study that may bear upon the Court's ultimate disposition. (Doc. 106. filed Apr. 21, 2009.)

II. DISCUSSION

A. Regulatory Framework

The FDCA provides that certain devices, such as the B-P Ankle, are subject to "premarket approval to provide reasonable assurance of it safety and effectiveness" before it can be shipped in interstate commerce. 21 U.S.C. § 360c(a)(l)(C). Because these devices must be shipped in interstate commerce in order to obtain premarket approval, however, the FDCA allows for an "investigational device exemption" ("IDE"). 21 U.S.C. § 360j(g). The exemption waives the prohibition on interstate shipment of a qualifying device "and permits the investigational use of unapproved devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices pursuant to protocol imposed by the FDA." *Endotec,* 563 F.3d at 1200-01.

***2** "To obtain an IDE exemption, a manufacturer must satisfy the requirements of 21 U.S.C. § 360j(g)as well as 21 C.F.R. § 812.20." *Id.* at 1201. Section 331(q)(1) of the FDCA expressly prohibits the failure or refusal to comply with any of the IDE requirements prescribed under § 360j(g). Furthermore, a failure to comply with the IDE requirements renders the device adulterated, and the FDCA proscribes the introduction into interstate commerce of any adulterated device. *See* 21 U.S.C. § 351(i) (defining device as adulterated if it fails to comply with IDE requirements); 21 U.S.C. § 331(a) (prohibiting the introduction or delivery for introduction into interstate commerce any adulterated or misbranded food, drug, device, tobacco product or cosmetic).

B. Is a Possible Violation of 21 U.S.C. §§ 33 J(q)(l) and 351(i) Moot?

Article III of the Constitution provides that federal courts may only consider active cases or controversies. U.S. Const. art. III, § 2. A case is moot, and therefore no longer an active case or controversy, "when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." *Powell v. McCormack,* 395 U.S. 486, 89 S.Ct. 1944, 23 L.Ed.2d 491. 496 (1969). Put differently, "the requisite personal interest that must exist at the commencement of the litigation (standing) must continue throughout its existence (mootness)." *Arizonans for Official English v. Ariz.,* 520 U.S. 43, 68 n. 22, 117 S.Ct. 1055, 137 L.Ed.2d 170 (1997).

After a 2001 inspection by the FDA in which numerous violations of the IDE were found, the agency issued Endotec an Application Integrity Policy hold ("AIP"). Under this policy, the FDA would defer review of further submissions by Endotec until it addressed the deficiencies identified in the inspection. On November 14, 2005, the FDA conditionally lifted the restrictions of the AIP to allow Endotec to initiate new clinical trials. (Doc. 111 at 4.) The conditions attached to the AIP removal were that Endotec had to submit a revised IDE protocol and submit to an FDA inspection to

ensure the integrity of the clinical study. To date, Endotec has not complied with these conditions. As a result, the ATP has not actually been lifted. Nonetheless, as discussed below, in the event that the AIP was lifted and the clinical trials resumed, Dr. Buechel still violated the terms of the IDE two years later in 2007 when he implanted an ankle device despite not being an authorized investigator under the IDE.

Defendants further argue that the case is moot because a decision has been made to voluntarily abandon the B-P Ankle as a copy of it is currently undergoing clinical trials. As a general matter, "voluntary cessation of allegedly illegal conduct does not deprive the tribunal of power to hear and determine the case, i.e., does not make the case moot." *County of Los Angeles v. Davis,* 440 U.S. 625, 631, 99 S.Ct. 1379, 59 L.Ed.2d 642 (1979) (citation omitted). When injunctive relief is sought, however, a claim may become moot if: "(1) it can be said with assurance that there is no reasonable expectation that the alleged violation will recur: and (2) interim relief or events have completely and irrevocably eradicated the effects of the alleged violation." *Reich v. OSHRC,* 102 F.3d 1200, 1201 (11th Cir.1997) (quotation and citation omitted). In evaluating the first element, the Court considers the following factors:

> ***3** (1) whether the challenged conduct was isolated or unintentional, as opposed to a continuing and deliberate practice; (2) whether the defendant's cessation of the offending conduct was motivated by a genuine change of heart or timed to anticipate suit; and (3) whether in ceasing the conduct, the defendant has acknowledged liability.

Sheelv v. MRI Radiology Network, P.A., 505 F.3d 1173, 1184 (11th Cir.2007). "The formidable, heavy burden of persuading the court that the challenged conduct cannot reasonably be expected to start up again lies with the party asserting mootness.' " *Id.* (quotations and citations omitted).

Here, Defendants fail to meet the first element.[FN1] The notion that current market conditions preclude the continued production and distribution of the ankle device does not make it absolutely clear that Defendants have totally abandoned their allegedly unlawful behavior. *See Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.,* 528 U.S. 167, 189, 120 S.Ct. 693, 145 L.Ed.2d 610 (2000) ("A case might become moot if subsequent events made it absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur."). The record contains evidence of hundreds of violations ranging from shipments to implantations. *Endotec,* 563 F.3d at 1191-92. It is impossible to characterize this behavior as isolated, unintentional, or reluctant. To the contrary. Defendants' conduct constituted a "continuing practice" that cautions against mootness. *Sheely,* 505 F.3d at 1185. And while Defendants cessation appears to have been spurred by economic reasons independent of this litigation, they have continually failed to concede any wrongdoing and are still urging the validity of their actions. Moreover, as a practical matter, the unpredictability of the market for orthopaedic implants and that of the other pending clinical study means that the Government cannot be sufficiently reassured that Defendants will comply with the FDCA's statutory prescriptions. If the demand for the B-P Ankle outstrips the supply of the current clinical trials, there is nothing in the record to indicate that Defendants would not step in to fulfill that need. What's more, Defendants would have an even greater incentive to reenter the market in the event that the current clinical study is unsuccessful.

> FN1. The Court, therefore, will not address the second element.

The same is true for Defendants' argument that the Eleventh Circuit failed to hold the government to its burden of showing why a permanent injunction is necessary despite the remedial measures implemented.[FN2] (Doc. 108 at 13.) This is nothing more than a recasting of Defendants' voluntary cessation argument. The Supreme Court has explained that in

a public enforcement action, the mere possibility of a recurrent violation "together with a public interest in having the legality of the practices settled, militates against a mootness conclusion." *United States v. W.T. Grant Co.*, 345 U.S. 629, 632, 73 S.Ct. 894, 97 L.Ed. 1303 (1953). Because Defendants refuse to expound on what the remedial measures implemented actually are, their assertion fails to erase the possibility of their resumption of illegal activity. Defendants implementation of some vague "remedial measures." therefore, does little to eliminate the likelihood of recurrence.

> FN2. In making this argument. Defendants misperceive this Court's role. If Defendants feel that the Eleventh Circuit has erred on a critical issue then their outlet for relief lies elsewhere. In any event, the Court of Appeals explicitly noted it was Defendants' burden to show compliance with the IDE and not the Government's burden to show otherwise. *Endotec,* 563 F.3d at 1195 . Additionally, it would be hard for the Government to show how the remedial measures were defective when the Defendants still have not disclosed what they were.

***4** Similarly, Defendants' contention that the sale of Endotec in January of 2009 renders the case moot fails. (Doc. 108 at 4.) To be sure, a case or controversy may become moot when a defendant is divested of responsibility for the challenged actions during the pendency of litigation. *See Miccosukee Tribe of Indians of Fl. v. So. Everglades Restoration Alliance,* 304 F.3d 1076, 1081 (11th Cir.2002) (denying claim for injunctive relief as moot against organization and its director when the organization had dissolved). When this occurs, the case becomes moot because either the plaintiff is no longer exposed to personal injury by the named defendant, or because a particular defendant can no longer comply with the relief sought to be imposed. *See* 15 James Wm. Moore *et al.*. Moore's Federal Practice § 101.94[3].

This, however, is not the present case. The Government, on behalf of public health and safety, continues to be exposed to harm by the individual defendants. Defendants' assertion concerning the sale of Endotec says nothing about any inventory under their control or their ability to continue to manufacture and implant the ankle device. Moreover, this is not a situation where the Court is being asked to prevent an event that has already occurred. The individual defendants have failed to put forward anything that would indicate an inability comply with a permanent injunction preventing the distribution of the B-P Ankle. Thus, the issue of whether Defendants violated the IDE is not moot.

C. Did Defendants Violate 21 U.S.C. §§ 331(q)(1) and 351(i)?

Defendants originally applied for and received conditional approval for an IDE study of the B-P Ankle in 1997. Two years later, in May of 1999, Defendants received full approval of the IDE for 109 patients. Full enrollment for the IDE was reached in 2001.

The Government maintains that Defendants violated the FDCA by failing to comply with numerous IDE regulations. Specifically, the Government points to evidence in the record that one of the clinical investigators, Dr. Feldman. implanted seventeen devices into seventeen different patients and ten more as "surgeon specials" completely outside the study, all without notifying Defendants.[FN3] Moreover, Dr. Buechel implanted 218 devices despite the fact that he was not an authorized investigator under the IDE clinical study. An FDA inspection also found numerous other regulatory violations. These include: employing faulty record keeping in that it was impossible to track the 109 authorized implants out of the 4000 in Endotec's database; selecting investigators with no prior experience conducting clinical studies; enrolling subjects in the study who failed to meet the clinical criteria; failing to take action when investigators submitted inadequate documentation of surgical follow-up;

and failing to address discrepancies in investigators' reports. (Doc. 111 at 6.)

> FN3. The term "surgeon specials" is one coined by the Defendants' and has no recognized legal meaning. To the contrary, as the Eleventh Circuit pointed out, this Court found that "surgeon specials ... and the purported custom ankle devices manufactured and distributed by the [Defendants], are one and the same." *Endotec,* 563 F.3d at 1189.

The most damaging evidence offered against the defendants, and that emphasized by the Eleventh Circuit, was Dr. Buechel's admission that he implanted the device on an unknown number of patients prior to receiving a warning letter from the FDA in 2002 and even occasionally since then. *Endotec,* 563 F.3d at 1201. Specifically, this Court originally found that

> ***5** Dr. Buechel admitted that he is not a clinical investigator for the B-P Ankle and that means he cannot implant B-P Ankles pursuant to the approved IDE. However, Dr. Buechel implanted B-P Ankles as surgeon specials until 2002 when FDA issued its warning letter to Endotec. Since 2002. Dr. Buechel has only implanted what he describes as custom ankle devices. Dr. Buechel admitted that in April 2007, he implanted an ankle device in which all the component numbers began with ' "05," indicating that it was the standard B-P Ankle. Dr. Buechel offered that the particular situation must have been an emergency situation. In other situations, Dr. Buechel used components that had been originally manufactured for another patient because it offered the patient the best fit.
>
> *United States v. Endotec, Inc.,* 2008 U.S. Dist. LEXIS 35427, at *18, 2008 WL 1909164.

In response. Defendants argue that §§ 331(q)(l) and 351(i) were not violated because any B-P Ankles manufactured and distributed outside the IDE were custom devices. (Doc. 108 at 6-10.) The Eleventh Circuit, however, expressly rejected the argument that the B-P Ankles manufactured and distributed after 2002 were custom devices. *Endotec,* 563 F.3d at 1201 n. 16. On one occasion an FDA inspector observed that after the shipment of a custom ankle device had been returned by the patient, it was merely relabeled and repackaged before it was shipped to another patient. This argument also willfully ignores Dr. Buechel's admission that he implanted a standard version of the ankle device as late as 2007. Defendants' argument that the devices distributed outside the study were not meant to determine their safety and effectiveness does not excuse them from exceeding the study's parameters. (Doc. 108 at 6.) The purpose of the IDE is to foster the development of useful devices by establishing their safety and effectiveness. 21 U.S.C. § 360j(g). To measure the IDE's application based on the intention of the sponsor would be to render the study's limits pointless. Defendants have therefore failed to rebut the record evidence that adulterated ankle devices were distributed well after the IDE reached full capacity in 2001. Accordingly, Defendants have violated 21 U.S.C. §§ 331(q)(l) and 351(i).

D. Is a permanent injunction appropriate?

Defendants argue that even in the event of statutory violations, injunctive relief is not warranted. Section 332 provides that "[t]he district courts of the United States ... shall have jurisdiction, for cause shown, to restrain violations of [331]." 21 U.S.C. § 332(a). Traditionally, a court will grant equitable relief if the moving party shows: (1) success on the merits; (2) irreparable injury will be suffered in the absence of an injunction; (3) the injury to the movant outweighs any damage the injunction will cause the opposing party; and (4) the injunction will be in the public interest. *Endotec,* 563 F.3d at 1194.

As the Eleventh Circuit has noted, when it comes to statutorily authorized injunctions, "no overarching

principles are readily apparent." *Klay v. United Healthgroup, Inc.*, 376 F.3d 1092, 1099 (11th Cir.2004). At least in the context of the Emergency Price Control Act of 1942, 50 U.S.C.S. § 901 (repealed 1956), the Supreme Court has taken the view that the traditional equitable factors should be satisfied before issuing a statutorily authorized injunction. *Hecht Co. v. Bowles*, 321 U.S. 321, 330, 64 S.Ct. 587, 88 L.Ed. 754 (1944) ("[I]f Congress desired to make such an abrupt departure from traditional equity practice as is suggested, it would have made its desire plain."). On the other hand, the Supreme Court has also held that in addition to showing a statutory violation. "[t]he necessary determination is that there exists some cognizable danger of recurrent violation." *W.T. Grant*, 345 U.S. at 633.

***6** By its terms, § 332(a) merely grants district courts with the discretion to issue an injunction prohibiting further violations of the FDCA; it does not mandate it. In the absence of further congressional guidance, courts have taken different approaches towards exercising this discretion. *Endotec*, 563 F.3d at 1194 n .9. While some courts have held that a violation of the FDCA alone is enough to justify injunctive relief, others have applied hybrid standards incorporating both the statutory violation and one or more other factors. *Compare United States v. Hoxsey Cancer Clinic*, 198 F.2d 273 (5th Cir.1952); [FN4] *United States v. Universal Mgmt. Servs.*, 999 F.Supp. 974, 977 (N.D.Ohio 1997) (noting that when a device is found to be adulterated, that "alone entitles the government to the injunctive relief it seeks.") (quotation omitted); *and United States v. Articles of Food and Drug*, 441 F.Supp. 772 (E.D.Wis.1977) (holding that no further showing beyond a statutory violation is required before injunctive relief can be granted) *with United States v. Odessa Union Warehouse Coop.*, 833 F.2d 172, 175-76 (9th Cir.1987) (considering the public interest as well as the likelihood of recurring violations) *and United States v. Diaulse Corp. of Am.*, 457 F.2d 25 (2d Cir.1972) (presuming public harm but considering the likelihood of continuing violation).

> FN4. In *Bonner v. City of Prichard*, 661 F.2d 1206 (11th Cir.1981), the United States Court of Appeals for the Eleventh Circuit adopted as binding precedent all decisions of the United States Court of Appeals for the Fifth Circuit handed down prior to the close of business on September 30, 1981.

Under the approach requiring only a statutory violation, the Eleventh Circuit's opinion in this matter and this Court's discussion in the previous section make clear that Defendants' violation of § 331 entitles the Government to an injunction under § 332(a). *See Endotec*, 563 F.3d at 1196-1200.

The Court further finds that injunctive relief is appropriate under a modified standard as well. As an initial matter, the Court is not aware of any decision requiring the Government to establish irreparable injury before issuing an injunction prohibiting further violations of § 331. *See, United States v. Nutri-Cology, Inc.*, 982 F.2d 394, 398 (9th Cir.1992); *United States v. Spectro*, 544 F.2d 1175, 1181 (3d Cir.1976); *Diapulse*, 457 F.2d at 28 (2d Cir.1972) (citing cases); *United States v. Livdahl*, 356 F.Supp.2d 1289, 1290-91 (S.D.Fla.2005); *United States v. Rx Depot, Inc.*, 290 F.Supp.2d 1238, 1246 (N.D.Okla.2003); *United States v. H.W. Andersen Prods., Inc.*, No. 2:95cv00315, 1997 U.S. Dist. LEXIS 3080, at *4 (M.D.N.C. Jan. 24, 1997); *United States v. Kasz Enters ., Inc.*, No. 930455P, 1994 U.S. Dist. LEXIS 8597. at *32: (D. R.I. May 6, 1994); *United States v. Richlyn Labs., Inc.*, 827 F.Supp. 1145, 1150 (E.D.Pa.1992); *United States v. Pro-Ag, Inc.*, 796 F.Supp. 1219, 1231 (D.Minn.1991). This principle reflects the underlying difference of purpose between an injunction sought by the sovereign pursuant to a statute and that sought by a private litigant. This difference is the pursuit of the public interest. *Hecht Co. v. Bowles*, 321 U.S. at 330 (explaining that it is "the standards of the public interest, not the requirements of private litigation, [that] measure the pro-

priety and need for injunctive relief"). Because "the passage of the statute is itself an implied finding by Congress that violations will harm the public." *Nutri-Cology, Inc.,* 982 F.2d at 398, the Court sees no reason to deviate from this approach and will not do so.

*7 For the same reasons that establishing irreparable injury is not required, many courts also do not balance the equities. *Universal Mgmt. Servs.,* 999 F.Supp. at 977; *Kasz Enters., Inc.,* 1994 U.S. Dist. LEXIS 8597, at *32; *Pro-Ag, Inc.,* 796 F.Supp. at 1231. Discarding this traditional factor coincides with the Supreme Court's admonition that "remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health." *United States v. An Article of Drug Bacto-Unidisk,* 394 U.S. 784, 798, 89 S.Ct. 1410, 22 L.Ed.2d 726 (1969). Additionally, balancing the equities can appear to be duplicative given the implication that Congress has already struck a balance between the public interest and private defendants in authorizing the remedy. Even applying this factor, however, the injury to the public interest from Defendants' persistent violation of § 331 outweighs any damage from a properly tailored injunction. Failing to enjoin Defendants from flouting FDA regulations would leave those who received the devices beyond the scope of the IDE and potential future recipients unprotected, render any data received from the IDE itself unreliable, and " 'deceive the public both as purchasers and users of the device." *Endotec,* 563 F.3d at 1202 (quotation and citation omitted).

Finally, a number of courts, including the Southern District of Florida, have adopted the approach outlined in *United States v. W.T. Grant,* 345 U.S. at 633. Specifically, "the requirements for injunctive relief are met when the government establishes that [D]efendants have violated the statute and there exists some cognizable danger of recurrent violation." *United States v. Sene X Eleemosynary Corp.,* 479 F.Supp. 970, 981 (S.D.Fla.1979) (quotation and citation omitted). *See also, H.W. Andersen Prods., Inc.,* 1997 U.S. Dist. LEXIS 3080. at *4; *Pro-Ag, Inc.,* 796 F.Supp. at 1231. Just as voluntary cessation does not deprive a court of jurisdiction, "the court's power to grant injunctive relief survives the discontinuance of the illegal conduct." *W.T. Grant,* 345 U.S. at 633; *United States v. Medwick Labs., Inc.,* 416 F.Supp. 832, 833 (N.D.Ill.1976). Establishing a cognizable danger of future violations, however, requires "more than the mere possibility which serves to keep the case alive." *W.T. Grant,* 345 U.S. at 633.

The Court finds that an appreciable threat of recurrent violations exists. Although evaluating the likelihood of future violations is inherently speculative and by no means taken lightly, the Court's conclusion is supported by the principle that despite the forward looking nature of injunctive relief, "[Defendant's] past conduct is a relevant factor to be considered." *Offner v. Shell's City, Inc.,* 376 F.2d 574, 576 (5th Cir.1967). The hundreds of devices shipped outside the scope of the IDE tlirough 2005 as well as Dr. Buechel's implantation of the device as recently as 2007 weigh heavily in favor of granting injunctive relief. Similarly, "[i]njunctive relief is particularly appropriate in cases such as this where violations are systemic and ongoing, notwithstanding repeated warnings by the FDA." *Kasz Enters., Inc .,* 1994 U.S. Dist. LEXIS 8597, at *34. Here, Defendants' persistent violations continued despite warnings from FDA investigators in 2002 and 2005. Endotec, 563 F.3d at 1191-92. Therefore, the Government has met its burden and a permanent injunction pursuant to 21 U.S.C. § 322(a) is warranted.

III. CONCLUSION

*8 Accordingly, it is hereby **ORDERED, ADJUDGED,** and **DECREED** that this Court's previous Order of April 21, 2009 (Doc. 106) is **AMENDED** to read:

1. With respect to the B-P Ankle, Defendants viol-

ate the FDCA, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce articles of device, as defined by 21 U.S.C. § 321(h), that are adulterated within the meaning of 21 U.S.C. §§ 351(f)(1)(A), 351(f)(1)(B) .

2. With respect to the B-P Ankle, Defendants violate the FDCA, 21 U.S.C. § 331(k), by causing articles of device to become adulterated within the meaning of 21 U.S.C. §§ 351(f)(1)(A), 351(f)(1)(B) , while such articles are held for sale after shipment of one or more of their components in interstate commerce.

3. With respect to the B-P Ankle, Defendants violate the FDCA, 21 U.S.C. § 331(q)(l), by causing articles of device to become adulterated within the meaning of 21 U.S.C. § 351(i), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

4. Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who have received actual notice of this Order by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any act that:

A. violates 21 U.S.C. § 331(a). by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce a B-P Ankle that is adulterated within the meaning of 21 U.S.C. §§ 351(f)(1)(A). 351(f)(1)(B); and

B. violates 21 U.S.C. § 331(k). by causing a B-P Ankle to be adulterated, within the meaning of 21 U.S.C. §§ 351(f)(1)(A), 351(f)(1)(B), while such article is held for sale after shipment of one or more of its components in interstate commerce.

C. violates 21 U.S.C. § 331(q)(1), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce a B-P Ankle that is adulterated within the meaning of 21 U.S.C. § 351(i).

5. Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert of participation with any of them who have received actual notice of this Order by personal service or otherwise, are enjoined pursuant to 21 U.S.C. § 332(a) from manufacturing, packing, labeling, and distributing the B-P Ankle device unless and until:

A.1. For the existing investigational device exemption (IDE), the Defendants submit a supplemental application requesting approval for a protocol deviation under 21 C.F.R. § 812.35(a) for the B-P Ankle in order to treat a specific patient and FDA approves, in writing, the IDE supplement: or

***9** A.2. There is an FDA approved application for premarket approval (PMA) filed pursuant to 21 U.S.C. § 360(e): or

A.3. FDA has received a premarket notification as required by 21 U.S.C. § 360(k) (also referred to as 510(k) submission) for the B-P Ankle and has advised Defendants in writing pursuant to 21 U.S.C. § 360c(l)(l)(A) that the device is substantially equivalent to a predicate device; and

B. Defendants submit a list(s) to FDA that includes the following information for each component or system included in the B-P Ankle in inventory as of the date of this Order, or that Defendants have distributed within one year prior to the entry of this Order: (1) the name and catalog number of the component or system; (2) a statement whether the component or system has been cleared for marketing under a premarket notification submission pursuant to 21 U.S.C. § 360(k) or is intended to be marketed under an IDE, PMA,

or other FDA clearance, exemption, or approval; (3) an engineering print for the component or system; (4) the component's or system's notification/application number (i.e., 510(k), IDE, or PMA); and (5) the component's or system's quantity and lot numbers; and

C. FDA reviews the list submitted pursuant to paragraph 5.B. and notifies Defendants, in writing, that they may commence manufacturing, packing, labeling, and distributing the components and systems for the B-P Ankle that meets the requirements of this paragraph.

6. Within thirty (30) calendar days of the entry of this Order, Defendants shall establish, implement, and continuously maintain a record-keeping system that records, at a minimum, the following information for each component that comprises each B-P Ankle system manufactured and distributed by Defendants: (a) the component's or system's name, catalog number, quantity, and lot number; (b) the name and address of the purchaser(s); (c) the date of sale; (d) a statement whether the component or system was marketed under a 510(k), IDE, PMA, or other FDA clearance, exemption, or approval; and (e) the component's or system's 510(k), IDE, or PMA number. Defendants shall submit a copy of the records kept pursuant to this system to FDA on a quarterly basis.

7. If, at any time after entry of this Order, FDA determines that Defendants have failed to comply with any provision of this Order, or have violated the FDCA or its implementing regulations, FDA may order in writing Defendants to cease all manufacturing, processing, packing, labeling, holding, and distributing of any or all device system(s), or any device(s), any of the components that comprise the finished device system(s), or any other device or component determined by FDA to be in violation of this Order, the FDCA, or its implementing regulations. FDA may also order in writing Defendants, as and when FDA deems necessary, to recall any device(s) that are adulterated or misbranded or are otherwise in violation of this Order, the FDCA, or its implementing regulations or take any other corrective action to bring Defendants and their products into compliance with this Order, the FDCA, or its implementing regulations. Defendants shall bear the costs of any recalls and any corrective actions ordered by FDA. Any cessation of operations described in this paragraph shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Order, the FDCA, and its implementing regulations.

***10** 8. Duly authorized representatives of FDA are authorized, as and when FDA deems necessary and without prior notice, to inspect Defendant's facilities in order to monitor and ensure continuing compliance with this Order. During such inspections, FDA representatives are authorized to inspect all equipment, finished and unfinished materials and products, containers, and labeling therein; to take photographs and make video recordings; to collect samples of any articles of device; and to examine and copy all records relating to the manufacture, packing, labeling, and distribution of any of Defendant's products. These inspections shall be permitted upon presenting a copy of this order and appropriate credentials. The inspection authority granted by this Order is separate from, and in addition to, the authority to make inspections under the FDCA, 21 U.S.C. § 374.

9. Within ten (10) calendar days after entry of this Order, Defendants shall provide a copy of this Order, by personal service or registered mail, to each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them. Defendants shall also post a copy of this Order in the employee common areas at their manufacturing facility. Within thirty (30) calendar days of the date of the entry of this Order, Defendants shall provide to FDA an affidavit of compliance, based upon personal knowledge of the affiant, stating the fact and manner of compliance with the provisions of this paragraph and identify-

ing the names and positions of all persons who have received a copy of this Order.

10. Defendants shall address all communication with FDA required under this Order to the Director. Florida District Office, U.S. Food and Drug Administration, 555 Winderley Place. Suite 200. Maitland. Florida 32751, and the Director, Office of Compliance for Devices and Radiological Health, 20904 Gaither Road, Rockville, Maryland 20850.

11. Should the United States bring and prevail in a contempt action to enforce the terms of this Order, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees, court costs, expert witness fees, and investigational and analytical expenses incurred in bringing such an action.

12. Defendants shall abide by the decisions of the FDA, which decisions shall be final. All decisions specified in this Order shall be vested in the discretion of the FDA, which discretion shall be reviewed, if contested, by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

13. This Court retains jurisdiction to issue such further decrees and orders as may be necessary to enforce or modify this Order and for granting such other relief as may be necessary and appropriate for the proper disposition of this proceeding.

***11** 14. All other pending motions are **DENIED** as moot.

DONE and **ORDERED.**

M.D.Fla.,2009.
U.S. v. Endotec, Inc.
Slip Copy, 2009 WL 3111815 (M.D.Fla.)

END OF DOCUMENT

EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

UNITED STATES OF AMERICA,

Plaintiff,

v. Civ. No. CV 06-6074-HO

CHARLES G. GOSSETT, an individual, **d/b/a PYRO ALUMINUM CO, d/b/a PYRO ALUMINUM, INC.,** and **d/b/a SURVIVAL, INC.,**

Defendant.

~~PROPOSED~~ ORDER OF PERMANENT INJUNCTION

Plaintiff, the United States of America, filed a Complaint for Injunction (Docket No. 1) against Defendant Charles G. Gossett, an individual, and served Defendant with process on April 21, 2006 (Docket No. 4). Defendant failed to answer or otherwise respond to the complaint. Accordingly, the Clerk of Court entered his default on August 18, 2006. (Docket No. 11.) On August 28, 2006, Plaintiff moved this Court to enter a default judgment and permanent injunction against Defendant. (Docket No. 13.) Plaintiff's motion is GRANTED.

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that:

I. This Court has jurisdiction of this matter pursuant to 28 U.S.C. §§ 1331, 1337, and 1345 and 15 U.S.C § 1267(a) and has personal jurisdiction over Defendant. Venue in this district is proper under 28 U.S.C. § 1391(b).

II. The Complaint for Injunction states a claim for relief against Defendant under the Federal Hazardous Substances Act ("FHSA"), 15 U.S.C. § 1261 *et seq.*, and the regulations issued thereunder.

III. Defendant is in default because he has failed to plead or otherwise defend, pursuant to Rule 55 of the Federal Rules of Civil Procedure.

IV. Defendant violated the FHSA as alleged in the Complaint. Since at least January 2006, defendant Gossett has violated 15 U.S.C. § 1263(a) by introducing or delivering for introduction into interstate commerce kits or components intended to produce fireworks that are banned hazardous substances.

V. For purposes of this Order, the following definitions shall apply:

A. "Oxidizer" means potassium chlorate, sodium chlorate, potassium perchlorate, sodium perchlorate, potassium nitrate, sodium nitrate, potassium permanganate, or ammonium nitrate.

B. "Fuel" means aluminum and aluminum alloys, magnesium, magnesium/aluminum alloy (magnalium), antimony sulfide, antimony trisulfide, potassium benzoate, sodium benzoate, sodium salicylate, sulfur, titanium, zinc, zirconium, or zirconium hydride.

C. "Defendant" means Charles G. Gossett, whether doing business under the name SurvivalOps, Survival, Inc., Pyro Aluminum Company, Pyro Aluminum, Inc., or any other name, and each of his current and future directors, officers, agents, employees, servants, attorneys, successor corporations, and those persons in active concert or participation with him.

D. "Banned hazardous substances" have the meaning set forth at 15 U.S.C. § 1261(q)(1), and include "[f]ireworks devices intended to produce audible effects (including but not limited to cherry bombs, M-80 salutes, silver salutes, and other large firecrackers, aerial bombs, and other fireworks designed to produce audible effects, and including kits and components intended to produce such fireworks) if the audible effect is produced by a charge of more than 2 grains of pyrotechnic composition. . . ." 16 C.F.R. § 1500.17(a)(3). They also include "[f]irecrackers designed to produce audible effects, if the audible effect is produced by a charge of more than 50 milligrams (.772 grains) of pyrotechnic composition . . . including kits and components intended to produce such fireworks . . . ." 16 C.F.R. § 1500.17(a)(8).

VI. Defendant is hereby permanently restrained and enjoined from participating in any transaction that involves selling, giving away, holding for sale, facilitating the distribution of or otherwise distributing any oxidizer, fuel, fuse, tubes, or end caps.

VII. Defendant is hereby further permanently restrained and enjoined from violating 15 U.S.C. § 1263(a) by selling, giving away, facilitating the distribution of or otherwise distributing any item where Defendant knows or has reason to believe that the recipient intends to use such item as a component of banned hazardous substances.

VIII. To ensure continuing compliance with the terms of this Order, investigators with the United States Consumer Product Safety Commission ("CPSC") shall be authorized to make inspections, at their discretion and without prior notice, of Defendant's facilities and records therein, and to take samples, copies of documents, and photographs. Such inspection authority granted by this Order is apart from and in addition to the authority to make inspections under 15 U.S.C. §§ 1270 and 1271. Such inspections shall be authorized upon presentation of a copy

of this Order and government credentials. During any such inspections, Defendant shall cooperate fully with the CPSC investigators by, among other things, promptly providing any investigator with all requested documents and immediate access to any of Defendant's facilities.

VII. If Defendant violates this Order and is found in civil or criminal contempt thereof, Defendant shall, in addition to other remedies, reimburse plaintiff for its attorney fees (including overhead), investigational expenses, and court costs relating to any contempt proceedings.

VIII. This Court retains jurisdiction of this action for the purposes of enforcing or modifying this Order and for the purpose of granting such additional relief as hereafter may be necessary or appropriate.

Dated this 8th day of Sept., 2006.

Michael C. Hogan
UNITED STATES DISTRICT JUDGE

SUBMITTED BY: /s/ Neil J. Evans
NEIL EVANS, OSB #96551
Assistant United States Attorney
(503) 727-1053

/s/ Jennifer E. Grishkin
JENNIFER E. GRISHKIN
Trial Attorney
(202) 514-9471
Attorneys for Plaintiff